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09/154,283	09/16/1998	ALFRED J. MOO-YOUNG	CBR-3.0-016	6743

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LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK  
600 SOUTH AVENUE WEST  
WESTFIELD, NJ 07090

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/154283

Applicant(s)

MOO-POUNB

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 11/19/02.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-15, 17-44 is/are pending in the application.
- Of the above claim(s) 1-15, 17-21 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-15, 17-21 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 23
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-15, 18 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The evidence provided by applicant to overcome *Suvisaari et al.* indicates that Dr. Lahteenmaki is the inventor of the claimed invention. Thus, the 131 declaration is not deemed convincing.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-15, 17 are rejected under 35 U.S.C. 102(a) as being anticipated by *Suvisaari et al.*

*Suvisaari et al* teach the claimed method for injections (abstract, figures 1-3).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 13-15, 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Tanabe et al* in view of *Suvisaari et al.*

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Tanabe et al teach Androgens which are useful in control of male fertility (Abstract). They may be administered alone (column 15, lines 35-36). They have been shown to be useful in male contraception (column 17 lines 54-58). Transdermal delivery injection, and implants are specified (column 17 line 33, column 18 lines 46, 59).

It would have been obvious to use 7-methyl 16-ene nortestosterone as a male contraceptive in view of Tanabe et al.

As to the claimed levels of LH and FSH as an indication of efficacy, such are well known in the art (see Suvisaari et al abstract).

Applicants point to a discrepancy in Tanabe et al that is recognized as an anomaly (column 27 lines 48-52). However, efficacy orally is clearly shown and noted (column 27 lines 42-45).

Applicant's argument concerning dosages is not Germaine in view of the fact that applicant's dosage claims are excluded from the rejection.

Claims 1-15, 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 "substantially" is vague; it can mean as much as 49% active other than the androgen. E.W. Bliss Co. (DC Nohio) 122 USPQ 238.

Applicants argue potential infringement. However, "consisting essentially of" is an alternative option.

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Claims 1-15, 17, 19-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants disclose the invention for an implant. However, there is no disclosure for other vehicles providing the same results. Given the low solubility of steroids, such vehicles will be nontrivial.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234.

Webman/tgd  
February 26, 2003

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